Remarks

The foregoing amendments are made to insert the required SEQ ID NO identifiers associated with each listed sequence in order to be in compliance with the sequence rules under 37 CFR §1.821-1.825. Furthermore, applicant notes that, having thoroughly reviewed the instant application, no sequence data consisting of four or more amino acids and/or ten or more nucleotides appears to be present on page 9 or in claims 6-8 that would require the submission of a sequence listing. Applicants respectfully point out that the listing of amino acids for example on page 9, lines 16-23 are not sequences but an attempt to define a structural formula via a list of amino acids that can be individually used in the formula at each of the designated positions. Therefore, applicant respectfully requests removal of that portion of the objection mailed February 28, 2007, or specific identification of said data that the office deems in violation of the sequence rules under 37 CFR §1.821(a).

Claim 6 has been amended to include additional amino acid options for X2, X4 and X5. Support for the amendment to claim 6 can be found at least in Figure 3. Claim 23 has been amended to correct a typographical error. No new matter is believed to be raised by these amendments.

The PTO requires the restriction of the claims in the above-identified application into one of the following four groups of claims.

Group I: Claims 1-14, 19-20, and 25 allegedly drawn to a peptide, a composition comprising said peptide, a pharmaceutical preparation comprising said peptide, a diagnostic composition comprising said peptide, and a purified polypeptide.

Group II: Claims 15-18, allegedly drawn to a method of diagnosing the presence of colon tumor cells in a patient.

Group III: Claims 21-23 allegedly drawn to a method of treating a patient suffering from colon cancer.

Group IV: Claim 24, allegedly drawn to a method of identifying a homing molecule that homes to a marker on a colon tumor cell.

The PTO further requires that if Group I is elected, further election of one of the species of claim 9 or the peptide of claim 11 must be elected.

Applicants provisionally elect Group I with traverse. Applicants also elect the species of claim 11 with traverse.

37 C.F.R. § 1.475 provides that national stage applications shall relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Such inventions possess unity of invention. The requirement of a single inventive concept is fulfilled when there is a technical relationship within the claimed subject matter involving one or more of the same or corresponding special technical features. The special technical feature must define a contribution that the claimed subject matter makes over the prior art.

Applicants note that claim 1 is drawn to a peptide that selectively binds to colon cancer cells, and that this limitation constitutes a special technical feature that defines a contribution that the claimed subject matter makes over the prior art. Thus, the pending claims all have the same corresponding technical feature. In providing the restriction requirement, the Examiner merely states that the ISA/US considers the groups different and based on this alone "considers the several invention do not share a special technical feature within the meaning of PCT Rule 13.2." However, the Examiner has provided no basis for this determination. Applicants respectfully remind the Examiner that PCT Rule 13.2 states that

> the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

Additionally, MPEP 1850 states that contributions over the prior art "should be considered with respect to novelty and inventive step." As alleged evidence of inventive step, the Examiner has put forth Wolfe et al. (2002) *J. Nuc. Med.* 43:392-9. The Examiner asserts that Wolfe et al. "teaches a colon cancer specific binding peptide." Applicants respectfully submit that this is not the case. In order for a reference to anticipate a claim each and every limitation of the claim must be present. Claim one recites "a peptide that selectively binds to colon cancer cells." Applicants define "selectively" in the specification on page 11, lines 8-9 where they state that a "peptide is 'selective' for bidning to tumor cells when it binds at least about twice as strongly to tumor cells as to normal cells." Wolfe et al. teach that E. coli heat-stable enterotoxin (STa) which does bind primary and metastatic colorectal tumors has as its receptor Guanylyl cyclase C (GC-C) (see page 393, column 1, second paragraph). Wolfe et al further teaches that GC-C is expressed not only by primary and metastatic colorectal tumors but also by adult intestinal epithelial cells (see page 393, column 1, second paragraph). Therefore, STa shows no preferential binding over non-cancerous intestinal epithelial cells. Moreover, the affinity studies

conducted by Wolfe et al. were only conducted with respect to the affinity for GC-C by STa and various analogs of STa and no effort was made to distinguished between cancerous and non-cancerous tissue expressing GC-C (see Figure 1, Table 1 and page 394, column 2, second paragraph). Thus, at best Wolfe et al. is silent with regards to selectivity. Because Wolfe et al. does not teach that STa binds with at least twice the affinity to colon cancer cells as to normal cells, all of the limitation of the claims have not been disclosed. Therefore, Wolfe et al. does not anticipate the claims and the Examiner has not met his burden for establishing a lack of unity of invention. Accordingly, Applicants submit that all of the pending claims possess unity of invention.

Additionally, Applicants respectfully submit that it is rule 37 C.F.R. § 1.475 that discusses the determination of unity of invention. In particular, 37 C.F.R. § 1.475(b) states that "claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations [emphasis added]." Rule 37 C.F.R. § 1.475(b) does not say that claims not falling within the listed categories requires or establishes a lack unity of invention. Rule 37 C.F.R. § 1.475(b)(2) further states that one of the allowed categories where unity of invention will be found is "a product and a process of use of said product." As noted above, the correct standard for determining unity of invention is stated in rule 37 C.F.R. § 1.475(a). This rule, as well as the Rule 37 C.F.R. § 1.475(b)-(e), are consistent with PCT Rule 13.2, which provides the exclusive standard for determining unity of invention in national stage applications. Accordingly, Applicants believe the present restriction requirement is improper and must be withdrawn. Therefore, Applicants respectfully request rejoinder of group II with group I to be in accordance with rule 37 C.F.R. § 1.475(b)(2).

Regarding the species elections, Applicants respectfully remind the Examiner that under 37 C.F.R. § 1.141, Applicants are allowed to claim a reasonable number of species. In particular, Applicants note that the species elections has a finite total of 109 species (108 species in claim 9 and 1 species in claim 11). Applicants respectfully point out that if a reasonable number of species is allowed it would be illogical for the patent office to limit a "reasonable number" to one species as this would frustrate the language of the rule which creates the reasonable number exception when there are "more than one species of an invention."

Moreover, Applicants submit that the Examiner has not met her burden of showing that the species are patentably distinct and/or would require additional searches. The Examiner has

merely concluded that such distinction exists and that additional searches would be required without providing any evidence to support this position. Applicants respectfully point out that election of species should not be required if the species claimed would be considered unpatentable over each other (see MPEP § 808.01(a)). Applicants urge that this point should be carefully considered by the Examiner in regard to the identified species. Notwithstanding this, applicants note that the restriction requirement does not provide sufficient basis to indicate that examination of more than one of the "species" would overly burden the Examiner.

For the above reasons, reconsideration or withdrawal of the restriction requirement is requested.

A Credit Card Payment authorizing in the amount of $795.00, representing the fee for a small entity under 37 C.F.R. § 1.17(a)(5) for a four (4) month Extension of Time and a Request for a four (4) month Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being transmitted by EFS-WEB on the date indicated below.

J. Gibson Lanier — Date 7/30/07